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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,566	02/19/2002	Audrey Goddard	P 2534-3	4737
9157	7590	01/11/2006	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,566

Applicant(s)

GODDARD ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22,26-28 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 is/are allowed.
- 6) ☒ Claim(s) 20,22,26-28 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/19/02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

The request filed on 09 December 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/869,566 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 09 December 2005 is acknowledged and entered. Following the amendment, claims 20, 22, 32 and 33 are amended.

Currently, claims 20, 22, 26-28 and 31-36 are pending and under consideration.

Withdrawal of Objections and Rejections:

The prior art rejection of claims 22, 26-28 and 33-36 under 35 U.S.C. 102(e) as being anticipated by Timans, US6,680,380, is withdrawn in view of applicant's amendment.

Formal Matters:

This application contains informal drawings, for example, Figures 16. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Further, the drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 C.F.R. §1.58(a) and §1.83. Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 C.F.R. §§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any Figures which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format (i.e. as SEQ ID NO:'s) and should further amend the specification accordingly to reflect the replacement of the Figure by the appropriate SEQ ID NO:.

Appropriate correction is required.

Claim 26 is objected to for using the open language of "further comprising". The claim is

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dependent from claim 22, which recites the closed language “consisting of”. As such, it is improper to use the open language in the dependent claim.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite for the recitation of “a polypeptide encoded by a nucleic acid sequence of nucleotide position from *about* 118 to *about* 618”. It is unclear what it is meant by “from *about* 118 to *about* 618” since codons of amino acids are well defined and exact.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 20, 22, 26-28 and 32-36 remain rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al., US2003/0091532 A1, for the reasons of record set forth in the previous Office Actions mailed on 27 September 2004, and 14 June 2005.

The teachings of Sims were reviewed in the previous Office Actions. Briefly, Sims discloses a human IL-1 related polypeptide, IL-1 zeta, which amino acid sequence (SEQ ID NO:3, 192 amino acids) comprises amino acids 33-203 of the present SEQ ID NO:5 with 100% sequence identity. Additionally, Sims teaches a fusion protein comprising the polypeptide and Fc of an antibody. Further, Sims teaches that the polypeptide of IL-1 zeta of SEQ ID NO:3 includes a putative pro-domain extending from amino acids 1 to x, where x is an integer from 20 to 50. As such, one of Sims's fragments, the fragment of amino acids 26-192 of SEQ ID NO:3, is 100% identical to the polypeptide fragment of residues 37-203 of SEQ ID NO:5 of the present invention. Furthermore, Sims teaches variants of the polypeptide, which have *one* or more deletions, insertions, or conservative substitutions

Applicants argument filed on 09 December 2005 has been fully considered, but is not deemed persuasive for reasons below.

At page 5 of the response, the applicant argues that Sims does not teach a polypeptide fragment of amino acid residues 37-203 that binds differentially to IL-18R ECD but not IL-1R ECD. This argument is not persuasive because Sims's polypeptide fragments encompass the present fragment of residues 37-203 of the present SEQ ID NO:5, with 100% sequence identity, and therefore, the functional properties such as differential binding to IL-18R ECD would be inherent for the Sims's polypeptide. As addressed in the last Office Action, in *In re Swinehart and Sfiligoj* ((CCPA), 169 USPQ 226, 1971), the Court held:

"Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; additionally", where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be an inherent characteristic of prior art, it possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on."

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In the instant case, Sims's polypeptide meets the structural and sequence limitation of the claims, and the polypeptides having the same sequence would inherently have the same functional property regardless whether the prior art explicitly discloses that property.

Conclusion:


Claim 31 is allowable.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/3/06